

PATENT
Docket No. 58210US004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fink et al.) Group Art Unit: 1647
Serial No.: 10/788,731) Examiner: Fozial M. Hamud
Confirmation No.: 6098)
Filed: 27 February 2004)
For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

FACSIMILE TRANSMISSION TO THE PTO

Mail Stop 16
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P.O. Box 1450
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FAX NUMBER: (571) 273-6500
Total Pages (including cover page): 18
Time: 11:40 am (Central Time)
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The following papers are being transmitted to the Patent and Trademark Office by facsimile transmission: Request for Refund (2 pgs); copy of Large Entity Facsimile Transmission Under Rule 1.8 (1 pg); Request for Continued Examination (RCE) Transmittal (1 pg); copy of Petition for Extension of Time (1 pg); Amendment and Response (11 pgs); redacted copy of page 1 of August 2007 statement for Deposit Account No. 13-4895 (1 pg).

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

Mueting, Raasch & Gebhardt, P.A.
Customer Number: 26813

October 8, 2007
Date

By: Christopher D. Gram
Christopher D. Gram
Reg. No. 43,643
Direct Dial 612/305-0412

CERTIFICATE UNDER 37 C.F.R. 1.18: The undersigned hereby certifies that this Facsimile Cover Sheet and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR § 1.6(d) to the Patent and Trademark Office addressed to the Mail Stop 16, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of October, 2007, at 11:40 am (Central Time).

October 8, 2007
Date

Signature: Sue Dombroske
Name: Sue Dombroske

If you do not receive all pages, please contact us at (612)305-1220 (ph) or (612)305-1228 (fax).

PATENT
Docket No. 58210US004

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Applicant(s): Fink et al.) Group Art Unit: 1647
Serial No.: 10/788,731)
Confirmation No.: 6098) Examiner: Fozial M. Hamud
Filed: 27 February 2004)
For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

REQUEST FOR REFUND

Mail Stop 16
Director of the USPTO
P.O. Box 1450
Alexandria, VA 22313-1450

In connection with the above-identified patent application, an incorrect charge of \$400 for claims in excess of twenty was charged to Deposit Account No. 13-4895.

Background

When the subject application was originally filed, Applicants paid for 55 total claims, and 4 independent claims.

In response to the first Office Action dated September 29, 2006, Applicants deleted two claims, and did not add any claims; thus, no additional claims fees were required.

In response to the second Office Action dated May 2, 2007, Applicants deleted 26 claims, and did not add any claims; thus, no additional claims fees were required.

There have been no further claim amendments in regard to the subject patent application; thus, no additional claims fees are appropriate.

Please find enclosed a copy of the Large Entity Transmittal Under Rule 1.8, the Request for Continued Examination (RCE) Transmittal, the Petition for Extension of Time, and the Amendment and Response, all filed on September 4, 2007 in response to the Office Action dated May 2, 2007. Also enclosed is a redacted copy of page 1 of the September 2007 statement for

Request for Refund

Applicant(s): Fink et al.

Serial No.: 10/788,731

For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

Page 2 of 2

Deposit Account No. 13-4895 showing the correct charges of \$790 for the RCE, and \$120 for the extension of time fee, and the incorrect charge of \$400 for claims in excess of twenty.

Conclusion

Applicants respectfully request the amount of \$400 be refunded to Deposit Account No. 13-4895.

If there are any questions concerning this request, please do not hesitate to telephone the undersigned attorney at 612/305-0412.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Mail Stop 16, Director of the USPTO, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8/8/07 day of October, 2007, at 11:50 a.m. (Central Time).

By: Sue Dombroske
Name: Sue Dombroske

October 8, 2007
Date

CDG/skd

Respectfully submitted

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612)305-1220
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By: Christopher D. Gram
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Applicant(s): Fink et al.) Group Art Unit: 1647
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FACSIMILE TRANSMISSION TO THE PTO

Commissioner for Patents
 Mail Stop RCE
 P.O. Box 1450
 Alexandria, VA 22313-1450

FAX NUMBER: (571) 273-8300
 Total Pages (including cover page): 15
 Time: 3:05 pm (Central Time)
 (Transmission must be complete by
 midnight eastern time.)

The following papers are being transmitted to the Patent and Trademark Office by facsimile transmission: Amendment and Response (11 pgs); Request for Continued Examination (RCE) transmittal (1 page in duplicate); Petition for Extension of Time (1 page)

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895.

Mueting, Raasch & Gebhardt, P.A.
 Customer Number: 26813
 By: Christopher D. Gram
 Christopher D. Gram
 Reg. No. 43,643
 Direct Dial (612)305-0412

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Facsimile Cover Sheet and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop RCE, P.O. Box 1450, Alexandria, VA 22313-1450, on this 4th day of September, 2007, at 3:05 pm (Central Time).

September 4, 2007
 Date

Signature: Dani Moroz
 Name: Dani Moroz

If you do not receive all pages, please contact us at (612)305-1220 (ph) or (612)305-1228 (fax).

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PATENT
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Applicant(s): Fink et al.) Group Art Unit: 1647
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)
 For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

PETITION FOR EXTENSION OF TIME

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. §1.136(a), it is respectfully requested that a one-month extension of time be granted in which to respond to the outstanding Office Action mailed 2 May 2007, thereby extending the date on which the period of response is set to expire from 2 August 2007 to 2 September 2007. Because 2 September 2007 falls on a Sunday, the request is effective for a carryover to 4 September 2007, the next business day.

Please charge PTO Deposit Account No. 13-4895 in the amount of \$120 to cover the required extension fee. Please charge any additional fees or credit any over-payment to PTO Deposit Account No. 13-4895.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 4th day of September, 2007, at 1:05 pm (Central Time).

By: Dani Marcos
 Name: Dani Marcos

Date

9/4/2007

Respectfully submitted
 By
 Mueting, Raasch & Gebhardt, P.A.
 P.O. Box 581415
 Minneapolis, MN 55458-1415
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 Customer Number 26813

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COPYPATENT
Docket No. 58210US004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fink et al.)	Group Art Unit:	1647
Serial No.: 10/788,731)	Examiner:	Fozia M. Hamud
Confirmation No.: 6098)		
Filed: 27 February 2004)		
For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY)		

AMENDMENT AND RESPONSE
UNDER 37 CFR §1.116

Commissioner for Patents
Mail Stop RCE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed 2 May 2007, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on the page entitled "Amendments to the Claims."

Remarks begin on the page entitled "Remarks."

COPY

Page 2 of 11

Amendment and Response

Serial No.: 10/788,731

Confirmation No.: 6098

Filed: 27 February 2004

For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1. (Previously Presented) A method of identifying a compound that selectively modulates at least one TLR-mediated cellular activity, the method comprising:
 - providing an assay to detect modulation of a TLR7-mediated cellular activity and an assay to detect modulation of a TLR8-mediated cellular activity;
 - performing the assay to detect modulation of a TLR7-mediated cellular activity using a test compound and human cells that naturally express TLR7;
 - performing the assay to detect modulation of a TLR8-mediated cellular activity using the test compound and human cells that naturally express TLR8; and
 - identifying the test compound as a compound that selectively modulates at least one TLR-mediated cellular activity if the test compound modulates the TLR7-mediated cellular activity to a different extent than it modulates the TLR8-mediated cellular activity.
2. (Previously Presented) The method of claim 1 wherein the compound modulates a TLR7-mediated cellular activity and does not modulate a TLR8-mediated cellular activity.
3. (Previously Presented) The method of claim 1 wherein the compound modulates a TLR8-mediated cellular activity and does not modulate a TLR7-mediated cellular activity.
- 4-8. (Canceled)
9. (Currently Amended) A method of identifying a target compound having a TLR modulation profile that conforms to a target TLR modulation profile, the method comprising:
 - selecting a target TLR modulation profile;

Amendment and Response

Serial No.: 10/788,731

Confirmation No.: 6098

Filed: 27 February 2004

For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

COPY

Page 3 of 11

determining the TLR modulation profile of a test compound by:

providing an assay to detect modulation of a first TLR-mediated cellular activity and an assay to detect modulation of a second TLR-mediated cellular activity,
performing the assay to detect modulation of the first TLR-mediated cellular activity using the test compound,

performing the assay to detect modulation of the second TLR-mediated cellular activity using the test compound, and

determining the extent to which the test compound modulates each TLR-mediated cellular activity; and

identifying the test compound as a target compound if the TLR modulation profile of the test compound conforms to the target TLR modulation profile.

10. (Original) The method of claim 9 wherein at least one TLR modulation profile comprises TLR6-mediated cellular activity.

11. (Original) The method of claim 10 wherein at least one TLR modulation profile comprises modulation of TLR6-mediated cellular activity.

12. (Original) The method of claim 11 wherein at least one TLR modulation profile comprises substantially no modulation of TLR7-mediated cellular activity.

13. (Original) The method of claim 9 wherein at least one TLR modulation profile comprises TLR7-mediated cellular activity.

14. (Original) The method of claim 13 wherein at least one TLR modulation profile comprises modulation of TLR7-mediated cellular activity.

Amendment and Response

Serial No.: 10/788,731

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For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

COPY

Page 4 of 11

15. (Original) The method of claim 14 wherein at least one TLR modulation profile comprises substantially no modulation of TLR6-mediated cellular activity.

16. (Original) The method of claim 14 wherein at least one TLR modulation profile comprises substantially no modulation of TLR8-mediated cellular activity.

17. (Original) The method of claim 9 wherein at least one TLR modulation profile comprises TLR8-mediated cellular activity.

18. (Original) The method of claim 17 wherein at least one TLR modulation profile comprises modulation of TLR8-mediated cellular activity.

19. (Original) The method of claim 18 wherein at least one TLR modulation profile comprises substantially no modulation of TLR7-mediated cellular activity.

20. (Original) The method of claim 9 wherein at least one TLR modulation profile comprises TLR9-mediated cellular activity.

21. (Original) The method of claim 20 wherein at least one TLR modulation profile comprises modulation of TLR9-mediated cellular activity.

22. (Original) The method of claim 9 wherein the target TLR modulation profile includes one or more TLR-mediated cellular activities that are not detectably modulated by a target compound.

23-24. (Canceled)

Amendment and Response

Serial No.: 10/788,731

Confirmation No.: 6098

Filed: 27 February 2004

For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

COPY

Page 5 of 11

25. (Previously Presented) A method of selectively modulating cells of the immune system, the method comprising:

identifying a first human immune system cell population that naturally expresses TLR7 and a second human immune system cell population that naturally expresses TLR8;

selecting a compound that modulates a TLR7-mediated cellular activity of the first cell population to a different extent than it modulates a TLR8-mediated cellular activity of the second cell population; and

contacting cells of the immune system with the selected compound in an amount effective to modulate a TLR-mediated cellular activity of at least one of the cell populations.

26. (Original) The method of claim 25 wherein the method further comprises determining the TLR expression profile of the first cell population and the TLR expression profile of the second cell population.

27. (Original) The method of claim 26 wherein the step of selecting a compound comprises comparing the TLR expression profile of the first cell population and the TLR expression profile of the second cell population with a TLR modulation profile of the compound.

28. (Original) The method of claim 25 wherein modulating cells of the immune system comprises detectably activating the cells or detectably inhibiting the cells.

29. (Original) The method of claim 25 wherein the compound modulates the first cell population and does not detectably modulate the second cell population.

30. (Original) The method of claim 25 wherein the compound modulates both cell populations.

COPY

Page 6 of 11

Amendment and Response

Serial No.: 10/788,731

Confirmation No.: 6098

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For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

31. (Original) The method of claim 25 at least one cell population is modulated *in vitro*.

32. (Original) The method of claim 25 wherein at least one cell population is modulated *in vivo*.

33. (Original) The method of claim 25 wherein at least one immune system cell population comprises plasmacytoid dendritic cells.

34. (Previously Presented) The method of claim 25 wherein at least one immune system cell population comprises monocyte-derived dendritic cells.

35-55. (Canceled)

56. (Previously Presented) The method of claim 25 wherein the compound modulates the second cell population and does not detectably modulate the first cell population.

Amendment and Response

Serial No.: 10/788,731

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COPY

Page 7 of 11

Remarks

The Office Action mailed 2 May 2007 has been received and reviewed. Claim 9 having been amended, claims 7, 8, 23, 24, and 35-55 having been canceled, the pending claims are claims 1-3, 9-22, 25-34, and 56. Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary

Applicants thank Examiner Hamud for the courtesy of the telephonic interview held August 16, 2007, including Examiner Hamud, inventor John Vasilakos, Ph.D., and Applicants' representative Christopher Gram.

Applicants discussed claims 1, 9, and 25 with regard to the rejections under 35 U.S.C. §112, first paragraph. Applicants' remarks centered on the knowledge of one skilled in the art at the time the invention was made. Those remarks are summarized in the comments provided below.

No firm agreement was reached. However, Applicants thank Examiner Hamud for the constructive discussion and guidance.

Claim Amendments

Claims 7, 8, 23, 24, and 35-55 have been canceled without prejudice.

Claim 9 has been amended to recite, in part, determining the TLR modulation profile of a test compound by providing an assay to detect modulation of a first TLR-mediated cellular activity and an assay to detect modulation of a second TLR-mediated cellular activity, performing the assay to detect modulation of the first TLR-mediated cellular activity using the test compound, performing the assay to detect modulation of the second TLR-mediated cellular activity using the test compound, and determining the extent to which the test compound modulates each TLR-mediated cellular activity. Support for the amendment may be found generally throughout Applicants' disclosure and in claim 1.

Amendment and Response

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COPY

Page 8 of 11

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 1-6, 9-22, and 25-34 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse.

Claims 1, 9, and 25 are the independent claims. Claims 4-6 are canceled. Each of claims 2, 3, 10-22, and 26-34 depends, directly or indirectly, from one of claims 1, 9, and 25. Thus, remarks that refer to one or more of claims 1, 9, and 25 apply equally to all claims that depend from the indicated independent claim.

With regard to claim 1, the Office Action contends that the claims do not recite how to perform the assay or what activity or result to measure (Office Action, page 4). During the telephonic interview, Dr. Vasilakos explained that one skilled in the art is aware of a multitude of different assays (e.g., cytokine secretion, co-stimulatory marker production, functional assays, etc.) that can be employed to detect whether and to what extent a compound modulates TLR7- or TLR8-mediated cellular activity. The assays, how to perform the assays, and the endpoint (that which is being measured) for each assay are well known to those skilled in the art. Applicants therefore respectfully submit that claim 1 meets the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

With regard to claim 9, the Office Action asserts that one skilled in the art would not know the positive steps of the claimed method. Claim 9 has been amended to recite steps that include providing an assay to detect modulation of a first TLR-mediated cellular activity and an assay to detect modulation of a second TLR-mediated cellular activity, performing the assay to detect modulation of the first TLR-mediated cellular activity using the test compound, performing the assay to detect modulation of the second TLR-mediated cellular activity using the test compound, and determining the extent to which the test compound modulates each TLR-mediated cellular activity. As noted with regard to claim 1, the assays, how to perform the assays, and the endpoint (that which is being measured) for each assay are well known to those

Amendment and Response

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COPY

Page 9 of 11

skilled in the art. Applicants respectfully submit, therefore, that claim 9 meets the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

With regard to claim 25, the Office Action asserts that one skilled in the art would not know which human cell type to select and again asserts that one skilled in the art would not know which cellular activity to test for. During the interview, Dr. Vasilakos stated that one skilled in the art would, indeed, know which cell populations naturally express TLR7 and/or TLR8. Claim 25 does not recite testing the activity of the compound. Rather, claim 25 recites a method that makes practical use of the observation that certain TLR agonists modulate TLR-mediated cellular activity to varying degrees. Thus, claim 25 contemplates having knowledge of a plurality of TLR agonist compounds, knowing the TLR modulation profile of each compound, and knowing the desired TLR-mediated cellular activities one wishes to modulate. One skilled in the art can then select the compound that modulates TLR7-mediated cellular activity and TLR8-mediated cellular activity in the desired fashion to achieve the desired mix of TLR-mediated cellular activities from a human immune cell population, and then obtain that desired mix of TLR-mediated cellular activities by contacting the selected compound with the immune cell population. Applicants respectfully submit that claim 25 meets the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

Therefore, Applicants respectfully submit that claims 1-6, 9-22, and 25-34 satisfy 35 U.S.C. §112, second paragraph, and request that the rejection be withdrawn.

The 35 U.S.C. §112, First Paragraph, Rejection (Enablement)

Claims 1-3, 25-34, and 56 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action acknowledges that Applicants' disclosure enables identifying a compound based on assays that includes culturing certain cells and measuring the expression of certain cytokines or co-stimulatory proteins. However, the Office Actions asserts

Amendment and Response

Serial No.: 10/788,731

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For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY

COPY

Page 10 of 11

that Applicants' disclosure does not reasonably enable one skilled in the art to practice the full scope of the claims—i.e., does not reasonably enable the claimed methods using all possible assays to detect TLR-mediated cellular activity. Applicants respectfully traverse.

As noted above with regard to the rejections under 35 U.S.C. §112, second paragraph, Dr. Vasilakos explained during the telephonic interview that one skilled in the art recognizes that a multitude of routine, well known assays can be employed to determine whether and to what extent a compound modulates TLR-mediated cellular activity. The assays, how to perform the assays, and the endpoint (that which is being measured) for each assay are well known to those skilled in the art. Thus, one skilled in the art is able to practice the full scope of the subject matter recited in claims 1-3, 25-34, and 56.

Applicants respectfully submit that claims 1-3, 25-34, and 56 meet the enablement requirement of 35 U.S.C. §112, first paragraph, and request that the rejection be withdrawn.

The 35 U.S.C. §112, First Paragraph, Rejection (New Matter)

Claims 1 and 25 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action asserts that claims 1 and 25 recite "...human cells that naturally express TLR7" and "...human cells that naturally express TLR8", but that support for these limitations is lacking in Applicants' disclosure. Applicants respectfully disagree.

Examples 3 and 4 demonstrate selective modulation of plasmacytoid dendritic cells (pDCs) and myeloid dendritic cells (mDCs). The cell populations are obtained from peripheral blood mononuclear cells (PBMCs), obtained from human whole blood. The Office Action notes that a human source of the whole blood is not identified in Applicants' specification.

Human PBMCs are the source material for examples demonstrating cytokine induction in human cells by TLR agonist compounds in various patents cited in Applicants' disclosure (page 1, lines 22-32) and incorporated by reference at page 41, line 31 through page 42, line 2. PBMCs derived from human whole blood for cytokine induction assays is described, for

Amendment and Response

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Page 11 of 11

example, in U.S. Patent No. 6,667,312 at column 91, line 55 through column 92, line 9; U.S. Patent No. 6,677,348 at column 150, lines 6-29; U.S. Patent No. 6,677,349 at column 167, lines 7-30; and U.S. Patent No. 6,683,088 at column 67, line 58 through column 68, line 11.

Applicants respectfully request that the rejection of claims 1 and 25 under 35 U.S.C. §112, first paragraph, be withdrawn.

Summary

It is respectfully submitted that the pending claims 1-3, 9-22, 25-34, and 56 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228

9/4/2007
Date

By: Christopher D. Gram
Christopher D. Gram
Reg. No. 43,643
Direct Dial (612) 305-0412

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 4th day of September, 2007, at 2:05 pm (Central Time).

By: Dani Mowry
Name: Dani Mowry

Deposit Account Statement

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Deposit Account Statement

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September 2007

Deposit Account Number:

134895

Name:

MUETING RAASCH & GEBHARDT PA

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UNITED STATES

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09/05 1	10788731	58210US004	1251	\$120.00	\$30,862.50
09/05 2	10788731	58210US004	1202	\$400.00	\$30,462.50
09/05 3	10788731	58210US004	1801	\$790.00	\$29,672.50

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PATENT
Docket No. 58210US004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Fink et al.)	Group Art Unit:	1647
Serial No.: 10/788,731)	Examiner:	Fozia M. Hamud
Confirmation No.: 6098)		
Filed: 27 February 2004)		
For: SELECTIVE MODULATION OF TLR-MEDIATED BIOLOGICAL ACTIVITY)		

AMENDMENT AND RESPONSE
UNDER 37 CFR §1.116

Commissioner for Patents
 Mail Stop RCE
 P.O. Box 1450
 Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed 2 May 2007, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on the page entitled "Amendments to the Claims."

Remarks begin on the page entitled "Remarks."

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